Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2099145	01/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Banner Health Physicians West Llc	3632 American Way, Casper, WY	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on Sysmex PoCH i100 operator's manual review, lack of documentation, instrument reagent log review, and interview with staff, the laboratory failed to follow the manufacturer's instructions to perform quality control with the change of diluent (D pack) reagent for two years of testing reviewed (January 2018 to January 2020). The laboratory performed approximately 2400 complete blood counts (CBCs) per year. Findings include: 1. The PoCHi 100 instrument manufacturer's operator's manual included instructions to perform quality control following reagent changes. 2. The laboratory lacked documentation of quality control performance following reagent changes prior to testing patient samples from January 2018 to January 2020. 3. The laboratory on board instrument reagent log recorded diluent reagent changes approximately every 3 to 5 days, (the lot number changing approximately once per month) and lyse reagent changed approximately once per month. 4. In an interview conducted on 01/28/2020 at approximately 1:10 P.M., testing staff stated they did not perform quality control when diluent or lyse reagents were changed prior to testing patient samples.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time

	of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on lack of a record system, billing records review, and interview with staff, the laboratory failed to maintain a record system that includes the records and dates of all potassium hydroxide (KOH) preparation of vaginal specimen testing for two years reviewed from January 2018 to January 2020. The laboratory estimated they performed approximately 260 tests per year. Findings include: 1. The laboratory lacked a system for testing personnel to record the dates and identification of all KOH specimen testing. 2. Billing records review included approximately 45 tests performed over 2 years of testing reviewed. The billing record collected records only for tests that were directly billed for the KOH test code. 3. In an interview conducted on 01/28 /2020 at approximately 11:30 A.M., the technical consultant stated the laboratory KOH testing personnel did not have a record system to record the dates for all of the specimens they applied KOH reagent to reveal the presence or absence of fungal elements in vaginal fluid specimens.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory director failed to maintain the quality assurance plan to monitor the Individualized Quality Control Plan (IQCP) for D Dimer and Troponin I tests at least annually for 1 of 2 years reviewed (2019). The laboratory performed approximately 200 D Dimer and 200 Troponin I tests per year. Findings include: 1. The laboratory implemented an IQCP in 2018 for Troponin and D Dimer unit use cartridge tests to reduce quality control frequency to once per new shipment or lot number and every 30 days after evaluating the quality control history of conformance, reagent storage compliance, instrument function checks, and testing personnel competency. 2. In an interview conducted on 01 /28/2020 at approximately 11:00 A.M., the technical consultant confirmed the director had not review the IQCP to ensure reagents, environment, test systems, testing personnel and sample collections were monitored to ensure the frequency of control performance provided accurate and precise D Dimer and Troponin I tests.